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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,648	12/05/2003	Young Kweon Choi	428.1036	2815

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EXAMINER	
KRASS, FREDERICK F	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,648	CHOI ET AL.	
	Examiner	Art Unit	
	Frederick Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Previous Rejections

Unless maintained infra, all previous rejections are withdrawn.

Obviousness Rejection

Claims 1-15 were rejected under 35 USC 103(a) as being unpatentable over Kim et al (WO 01/68045 A1) in view of Moro et al (USP 6,585,997 B2).

This rejection is maintained.

Applicant argues that no case of obviousness exists since the primary reference "contains a hydrophilic glass polymer merely selected from the specified groups" and "does not require or intend to contain the erodible complexes formed by hydrogen bonding between the carboxyl-group containing polymer and the carbonyl or ether group-containing polymer." (Remarks, page 9, first full paragraph; emphasis original).

This argument is not persuasive. As pointed out in the previous Office Action at page 5, the tooth adhesion layer of the primary reference contains a mixture of polyalkyl vinyl ether-maleic acid copolymer, polyvinyl pyrollidone, and hydrogen peroxide. Complex formation would be inherent and indeed expected from the corollary disclosure at page 15, lines 30-34, as also previously discussed. Moreover, there is no requirement of patent statute, rule or case law that the motivation for the prior art's inclusion of given components be the same as Applicant's.

Applicant further argues that the primary and secondary references are not combinable since the primary reference relates to tooth whitening and the secondary reference to transmucosal patches which adhere to mucosal tissues. (Remarks, page 9, fourth full paragraph). More specifically, Applicant notes:

> In the tooth whitening patches, the polymers become hydrated by small amount of moisture on teeth. The hydration provides sufficient strength for the tooth patches to remain on teeth. (See page 29, lines 10-15 of the specification). In the transmucosal patches, the polymer chains, however, penetrate into mucosal tissues. At the interface of the polymers and mucosal tissues, mucin released from the mucosal tissues interacts with the polymers, which provides adhesion strength for the transmucosal patches. (Remarks, page 9, fourth paragraph).

Thus, Applicant concludes, "the tranmucosal patches adhere in a fundamentally different way than the tooth whitening patches" such that the secondary reference cannot suggest tooth whitening patches.

This argument is not persuasive. While Applicant's analysis is factually correct with respect to the specific documents cited, it is the examiner's positions that it fails to take into account the full scope of the state of the art. Bioredobile transmucosal patches of the type disclosed in the secondary reference are in fact known to deliver drugs when adhered to teeth as well as mucosal tissues; see Tapolsky et al (USP 5,800,832). Furthermore, transucosal patches are known to be equally effective in delivering both pharmaceutical actives (such as those of the secondary reference) and dental agents. See Schiraldi et al (USP 4,713,243) at column 3, lines 35-57, and at the passage bridging the bottom of column 2 to the top of column 3, for instance. (These references are cited herein only to rebut the factual evidence relied upon in Applicant's arguments (the three journal articles) and are not being incorporated substantively into the previous ground of rejection).

Finally, Applicant argues that:

> Contrary to what the Examiner has contended, even if those skilled in the art modify the tooth whitening patches of Kim et al. as taught by Moro et al., it does not make the claimed invention obvious. The tooth whitening patches of Kim et al. adapted as taught by Moro et al. do not contain the required erodible complexes of the adhesion layer. The tooth whitening patches of the present invention allow controlling erosion rate and adherence time to the teeth by a combination of modifying the type and proportions of the polymer components of the tooth-adhesion layer, and the erosion rate-controlling layer." (Remarks, page 10, second paragraph; emphasis original).

Again, this line of argument is not persuasive. As pointed out in the previous Office Action at page 5, the tooth adhesion layer of the primary reference contains a mixture of polyalkyl vinyl ether-maleic acid copolymer, polyvinyl pyrollidone, and hydrogen peroxide. Complex formation would be inherent and indeed expected from the corollary disclosure at page 15, lines 30-34, as also previously discussed. Moreover, there is no requirement of patent statute, rule or case law that the motivation for the prior art's inclusion of given components be the same as Applicant's (as apparently argued at pages 7-9 of the Remarks). That the methods (mechanisms) for controlling release and residence time may or may not be different in each case is not relevant to the instant claims, which are limited to products.

Action is Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached on Monday-Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614